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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,728	08/27/2001	Gwyn A. Cutsforth	2194-0042-23	2779

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ALEXANDRIA, VA 22314

EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,728

Applicant(s)

Cutsforth et al.

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 4, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above, claim(s) 1-20, 38-56, and 62-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-37, 57-61, and 85-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

Applicant's election with traverse of a compound providing a cation of the lanthanide series as the one or more metal compound, and thrombomodulin or recombinant thrombomodulin as the reagent in Paper No. 9 is acknowledged. The traversal is on the ground(s) that no reasons are provided for the patentable distinctness. This is not found persuasive because the inventions are properly restricted because they are independent and distinct for the reasons given.

The requirement is still deemed proper and is therefore made FINAL.

The IDS received 4/4/2003 has been entered and claims 1-87 are currently pending in this application, claims 21-37, 57-61, 85-87 are considered here. Priority is granted to 8/27/2001. In claim 24 line 2, ~~groups~~ may be intended to be ~~group~~. Issues under 35 USC 112 will be considered after the election and art issues are resolved.

A reading of the specification reveals on page 7 last paragraph, metal cations that interact with calcium binding sites include: manganese or magnesium or terbium or gadolinium, or europium, or lanthanum, which are used to increase the range of the assay by providing greater detection differences between samples with low amounts of the particular clotting parameter being measured and high amounts of the clotting parameter being

measured. No distinction is seen between the listed metal cations. In present claim 23 they are all a member of a Markush group and so are considered equivalents as claimed. On page 9 last paragraph and page 10 last paragraph of the present specification, thrombomodulin is a Protein C activator which is known in this art. A search reveals lanthanides for their claimed function are novel. However, Mn⁺² and Mg⁺² for the same function are known in the art.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

examiner to consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5 Claims 21-37, 57-61, 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosen.

 Rosen (6,395,501) entitled ~~✕~~In vitro Methods for Screening For Blood Coagulation Disorders Using Metal Ions~~✕~~ with a 102(e) date of 3/1998, teaches in column 2 last paragraph bridging to
10 column 3, thrombomodulin activates Protein C and is used in determining Protein C. In column 4 last full paragraph, the addition of divalent metal ions enhances the anticoagulant activity of the Protein C anticoagulant pathway providing for a high degree of resolution between different levels of Protein C
15 activity and an improved sensitivity and specificity for detecting defects in the Protein C pathway with clotting methods. In column 10 last paragraph, thrombomodulin and recombinant thrombomodulin are activators of Protein C.

 The claims differ from Rosen in that they specify or
20 encompass additional metal ions to those taught by Rosen. It is noted that lanthanides are generally trivalent cations.

 It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any metal ions desired to enhance the anticoagulant activity of Protein C
25 because Rosen teaches metal ions in general as well as Mg⁺² and

Mn+2 specifically. No distinguishing feature or special function for lanthanides is presently claimed.

5 The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

10 Spillert (6,245,573) teaches determining coagulation.

Lassen (US 2002/0132370 A1) teaches blood coagulation.

Mullinax (6,030,840) teaches lanthanides.

Krauss (6,482,653) teaches coagulation.

Bartl (5,001,069) teaches determining Protein C.

15 Hofstraat (WO 98/39654) teaches lanthanides.

Pittet (FR 2,689,640) teaches determining Protein C.

Kraus (US 2003/0027235 A1) entitled ~~Novel~~ Novel Method and Diagnostic Agent for Hemostasis Diagnosis~~with~~ with a 102(e) date of 12/98,

teaches in paragraph 42, europium compounds. In paragraph 46,

20 Protein C can be determined.

Serial No. 09/938,728
Art Unit 1651

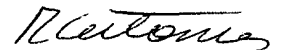
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.

5 The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status

10 of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business Center for more information.

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Ralph Gitomer
Primary Examiner
Group 1651

RALPH GITOMER
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GROUP 1200